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Attorney Docket No. 054707-103

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant: Joseph P. STEINER et al.

Title: PIPECOLIC ACID DERIVATIVE
HAIR GROWTH
COMPOSITIONS AND USES

Appl. No.: 09/781,427

Filing Date: 02/13/2001

Examiner: Rebecca Cook

Art Unit: 1614

APPEAL BRIEF UNDER 37 C.F.R. § 1.192

Commissioner for Patents
Washington, DC 20231

Sir:

This brief answers the final Office Action of February 15, 2002. It is filed with two additional copies of the originally signed brief. It is accompanied by the small entity fee of \$160 under 37 C.F.R. § 1.17(c). It is timely, since it is filed within four months of the Notice of Appeal dated June 12, 2002, and accompanied by a Petition for an Extension of Time and the fee of \$200 under 37 C.F.R. § 1.17(a)(2).

I. Real Party Interest

GPI NIL Holdings, Inc. is the real party in interest.

II. Related Appeals and Interferences

The following case is related: (1) 09/784,174, filed February 16, 2001. The

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Appeal number has yet to be given.

III. Status Of Claims

Claims 11-20 are pending. Claims 1-10 are cancelled. Claims 11-14 and 17 are appealed.

IV. Status Of Amendments

All amendments were entered.

V. Summary Of Invention

The present invention concerns a composition comprising an effective amount of a specified compound for treating alopecia or promoting hair growth in an animal; a second hair revitalizing agent; and a pharmaceutically acceptable carrier. Specification, p. 4, ll. 13-18; claim 11 (twice amended).

VI. Issues

There are three issues presented for review:

- A. whether claim 17 is patentable under 35 U.S.C. § 112, first paragraph (enablement of use);
- B. whether claims 11-14 are patentable under 35 U.S.C. § 103(a) over the teachings of CA128:43577; and
- C. whether claim 11 is patentable under the judicially created doctrine of obviousness type double patenting over claims 5-6 of copending application no. 09/784,174.

VII. Grouping Of Claims

For the purpose of this appeal only, the claims stand or fall together for each ground of rejection which Appellant contests and which applies to a group of two or

more claims.

VIII. Argument

A. The enablement of use rejection of claim 17 is improper and should be reversed, because the evidence and explanation fail to cast doubt on the present specification's presumptively enabling disclosure.

Claims are assumed enabled. MPEP § 2164.04. When challenging a claim's enablement, the PTO must not only explain why it doubts the claim's presumptively enabling disclosure but also cite supporting evidence for its assertion. Id. The explanation must include specific technical reasons that cast doubt on the claim's enablement. Id.

Both "promoting hair growth" and "treating alopecia" are asserted utilities of the claimed invention. Specification, p. 10, ll. 14-17. According to the present specification, "[p]romoting hair growth" refers to "maintaining, inducing, stimulating, accelerating, or revitalizing the germination of hair," and "[t]reating alopecia" refers to "(i) preventing alopecia in an animal which may be predisposed to alopecia; and/or (ii) inhibiting, retarding or reducing alopecia; and/or (iii) promoting hair growth; and/or (iv) prolonging the anagen phase of the hair cycle; and/or (v) converting vellus hair to growth as terminal hair." Specification, p. 9, l. 21 – p. 10, l. 5. In the present rejection, the Examiner's explanation consists of one specific finding addressing merely one of the two asserted utilities, namely, a compound of the claimed invention fails to initiate hair growth. Office action of 2/15/2, p. 2, ll. 12-13 ("CA122:230322 discloses that rapamycin does not initiate hair growth.").

Even if a single compound of the claimed invention were known to have failed to initiate hair growth, the explanation and evidence of record provide no basis to

infer that the same compound would not treat alopecia. Since claims are presumed enabled, and since the explanation and evidence of record provide no basis to infer that any claimed compound would not treat alopecia, nothing of record casts doubt on claim 17's enablement. Thus, the rejection should be reversed for this reason alone.

Second, a single inoperable embodiment does not necessarily render a claimed invention nonenabled. In re Angstadt, 537 F.2d 498, 502-03, 190 USPQ 214, 218 (CCPA 1976). The record never addressed whether undue experimentation is required to determine operable embodiments, nothing of record casts doubt on claim 17's enablement. Thus, the rejection should be reversed for this reason alone.

B. The rejection of claims 11-14 as prima facie obvious over the teachings of CA128:43577 is improper and should be reversed, because the prior art of record fails to suggest the desirability of the claimed invention according to the evidence and explanation of record.

The prior art must suggest a motivation to reach the claimed invention. MPEP § 2143.01. Such is not the case here.

In this rejection, according to the Examiner, CA128:43577 discloses a compound of the claimed composition, FK506, but not "a second agent that promotes hair growth." Office action of 9/17/1, p. 3, ll. 10-13. The Examiner, nevertheless, proposed to add "a second agent that promotes hair growth" to the composition of CA128:43577, because "it would be obvious ... to combine two compounds, each of which promote[s] hair growth, in a composition ... to increase the amount of hair growth." Id., p. 3, ll. 14-17.

But it is submitted that this motivation is not in the prior art. Just because

references can be modified to reach the claimed invention differs from a desirable reason for making that modification. MPEP § 2143.01. And a desirable reason for making that modification cannot be inferred from implying that one of ordinary skill in the art would have been capable of reaching the claimed invention. Id. Thus, the rejection is improper and should be reversed.

C. The rejection of claim 11 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-6 of copending U.S. Application No. 09/784,174 is improper and should be reversed, because the evidence and explanation of record fail to support the rejection.

A factual finding that is material to patentability can neither stand if it is supported only by conclusory statements nor be resolved only on the subjective belief of an examiner. In re Lee, 277 F.3d 1338, 1346, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002). A material finding is the motivation to combine/modify in the section 103 context. Id. Since determinations of *prima facie* obviousness in the section 103 context parallel those in the double patenting context, MPEP § 804 II. B. 1, any core factual determination in the double patenting context is material to patentability. Thus, a core factual determination in the double patenting context can neither stand if it is supported only by conclusory statements nor be resolved only on the subjective belief of an examiner.

At best, the Examiner implicitly urged that the present claims and those of the '174 Application overlap. But overlap and double patenting are two contrasting issues. MPEP §804 II. ("Domination" is analogous to overlap.). One set of claims overlaps a second set if the first set has a broad claim which encompasses an invention of the second set. Id. Overlap itself, however, cannot support a double

patenting rejection. Id. Thus, this rejection is improper and should be reversed, as it is based on a mere conclusion or a subjective belief.

IX. Appendix

An appendix containing a copy of the claims involved in the appeal is attached.

X. Conclusion

Each rejection should be reversed.

Respectfully submitted,

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If any [further] extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this Appeal Brief, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 19-0741.

APPENDIX

11. A pharmaceutical composition which comprises:
 - (iv) an effective amount of a compound having a six-membered heterocyclic ring with a single nitrogen heteroatom, which has an N-linked ketone, diketo, or thioketo substituent attached to the heterocyclic ring, and which is additionally substituted with an ester or amide substituent attached to the heterocyclic ring, provided that said ester or amide substituent is not an N-oxide of an ester or amide for treating alopecia or promoting hair growth in an animal in need thereof;
 - (v) a second hair revitalizing agent; and
 - (vi) a pharmaceutically acceptable carrier.

12. The pharmacological composition of claim 11, wherein the compound has an affinity for an FKBP-type immunophilin.

13. The pharmaceutical composition of claim 12, wherein the FKBP-type immunophilin is FKBP-12.

14. The pharmacological composition of claim 11, wherein the compound is immunosuppressive.

17. A pharmaceutical composition which comprises:

- (i) an effective amount of rapamycin;
- (ii) a second hair revitalizing agent; and
- (iii) a pharmaceutically acceptable carrier.